



Notice of Proposed Rulemaking for the Disposal of Controlled Substances

Case 3:17-cv-01362 Document 1149-8 Filed 10/30/20 Page 1 of 40 PageID #: 40016

➤ The NPRM on disposal was published in the Federal Register on December 21, 2012

➤ Open for a 60-day public comment period / Closed February 19, 2013

➤ The Final Rule will be published in the Federal Register upon completion

73784

Federal Register/Vol. 77, No. 246/Friday, December 21, 2012/Proposed Rules

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, 1307, 1317, and 1321

(Docket No. DEA-398)

RIN 1117-AD15

Disposal of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This rule proposes requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users. These regulations would implement the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111-273) by

expanding the options available to collect controlled substances from ultimate users for purposes of disposal to include take-back events, mail-back programs, and collection receptacles.

These proposed regulations contain specific language to continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection receptacles. In addition, this proposed rule expands the authority of authorized retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities. This proposed rule also addresses and consolidates existing regulations on disposal, including the rule of reverse distributors.

DATES: Electronic comments must be submitted and written comments must be postmarked on or before February 19, 2013. Comments should be marked that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-398" on all electronic and written correspondence. DEA encourages all comments to be submitted electronically through <http://www.regulations.gov> using the electronic comment form posted on this site. An electronic copy of this document is also available at <http://www.regulations.gov> Web site for easy reference. Paper comments that

duplicate the electronic submission are not necessary as all comments submitted to <http://www.regulations.gov> will be posted for public review and are part of the official docket record. Should you, however, wish to submit written comments via regular or express mail, they should be sent to the Drug Enforcement Administration, Attention: DEA Office of Diversion Control (DDA-2K), 8701 Morrisville Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: John W. Partridge, Executive Assistant, Office of Diversion Control, Drug Enforcement Administration, Mailing Address: 8701 Morrisville Drive, Springfield, Virginia 22152; Telephone (202) 305-4654.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and are made available for public inspection online at <http://www.regulations.gov> and in the DEA's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you would like to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you would like to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also place all the confidential business information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

Personal identifying information not identified and located as set forth above will be redacted, and the comment, if submitted, will be posted online and placed in the DEA's public docket file. Please note that the President of

information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

Docket:

I. Executive Summary

A. Purpose of the Regulatory Action

B. Summary of the Regulatory Action

C. Background

D. Legal Authority

E. History of Disposal of Controlled Substances

F. Existing DEA Regulations

G. Description of the Regulatory Action

H. Disposal of Controlled Substances by Ultimate Users—Authorized Methods

I. Disposal of Controlled Substances by Registrants

J. Reverse and Retail

K. Collection Receptacles

L. Miscellaneous Comments

M. Regulatory Analysis

Executive Summary

Purpose of the Regulatory Action:

On October 12, 2010, the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act) was enacted (Pub. L. 111-273, 124 Stat. 2838). Before the Disposal Act, ultimate users who wanted to dispose of unused, unwanted, or expired controlled substances generally could not dispose of them. The Disposal Act authorized the DEA to require those substances to be disposed of by crushing or incinerating, or to dispose of such substances by surrendering them to law enforcement or by seeking assistance from the U.S. Drug Enforcement Administration (DEA). Those substances resulted in the accumulation of controlled substances in household medicine cabinets that were available for abuse, misuse, and accidental ingestion. The Disposal Act authorized the DEA to authorize ultimate users to deliver their controlled substances to another person for the purpose of disposal in accordance with regulations promulgated by the Attorney General, 21 U.S.C. 822(g) and 828(b)(3). The Attorney General delegated responsibility for promulgating the Disposal Act implementing regulations to DEA. These proposed regulations expand the methods by which ultimate users may dispose of unused, unwanted, or expired controlled substances for the purpose of disposal, as well as the methods by which such non-hazardous substances may be collected. Specific entities may voluntarily administer any

NextOnline - 77 Fed. Res. 73784-2012

U.S. Drug Enforcement Administration / Operations
Division / Office of Diversion Control

CONFIDENTIAL

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Doctor Shopping





Doctor Shopping: What is it ?

Practiced by both Individual “Patients Drug Seekers” & Trafficking Organizations

- Target Physicians
 - Obtain prescriptions from multiple physicians
 - Physicians who are willing to prescribe controlled substances over an extended period of time with little or no follow-up
- Target Pharmacies
 - Utilize multiple pharmacies to fill the orders to avoid suspicion
 - Pharmacies known to dispense controlled substances without asking questions are targeted



Doctor Shopping: What is it?

Los Angeles Times

LATIMES.COM

Prescriptions like candy

The story of a Duarte doctor makes it clear a lot can go wrong between the handcuffs and the prison time.

SANDY BANKS

We're getting tough on drug dealers in Los Angeles these days, sweeping crack sellers off skid row streets, shutting down marijuana dispensaries, prosecuting doctors who peddle prescriptions like candy to patient addicts.



But the story of Dr. Daniel Healy makes it clear that a lot can go wrong between the handcuffs and the prison time.

Healy, according to prosecutors, is a most prolific drug dealer. In 2008 alone, he illegally distributed enough prescription drugs to constitute the federal government's equivalent of more than 50 kilos of cocaine or 37,900 pounds of marijuana.

The Duarte physician ordered more Vicodin than any doctor in the nation — 1 million pills in 2008. That's 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target and City of Hope pharmacies combined.

According to federal legal briefs, Healy made so many over-the-counter sales from his "Kind Care" medical clinic, the office had its own money-counting machine and Healy pocketed "\$3,000 to \$8,000 a day."

On the day he was arrested, police pulled over a

ghetto street dealer with a wad of cash and pocketful of crack cocaine.

That guy would have

received years in

little as f

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legal papers said.

Healy's dealings became

so blatant, local pharma-

cists refused to fill prescrip-

tions he wrote for his pa-

tients' prescriptions be-

cause they came in so often,

involved large quantities of

controlled substances and

patients tended to pay in

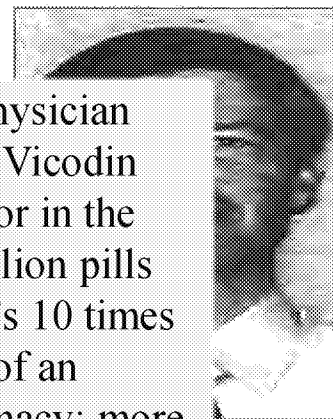
cash for the drugs.

Investigators matching

his inventory against his

pharmacy orders and pre-

The Duarte physician ordered more Vicodin than any doctor in the nation — 1 million pills in 2008. That's 10 times the stockpile of an average pharmacy; more than his local CVS, Wal-Mart, Target, and City of Hope pharmacies combined.



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Care clinic
An a "nar-

netted him
almost \$700,000 in one year:
"a cash-and-carry narcotics
store under the guise of
providing legitimate medi-

cal treatment."
The prosecutor in the
case stopped short of saying
he's disappointed when I
interviewed him Monday.

"Forty-eight months is a
significant sentence, by any
measure," said Assistant
U.S. Atty. David Herzog.

The felony conviction

means Healy will lose his license. "The end result is that this defendant is no longer able to distribute narcotics into the community and never will again."

But 48 months is considerably less than the 210-month minimum term the probation report recommended. It's less, even, than the 57 months Healy's lawyer suggested would be fair.

That's a blow to DEA efforts to crack down on abuse of prescription drugs, which is rising among teens and young adults.

Nearly 7 million Americans are abusing pharmaceutical drugs — up from 3.8 million 10 years ago, and more than the number addicted to cocaine, heroin and hallucinogens. Opioid painkillers — the kind Healy dispensed — cause more overdose deaths than cocaine and heroin combined.

Blatant drug-dealing by doctors is rare. More common is doctor-shopping by patients, thefts from pharmacies, trading meds by addicts and illicit street sales by drug dealers.

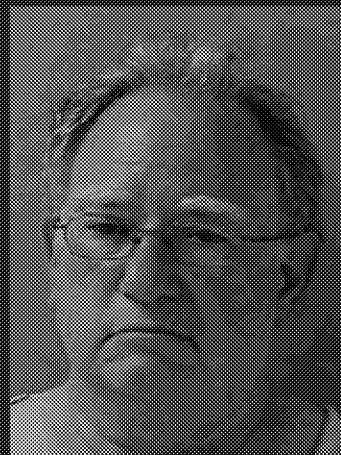
That's why Healy's sentence is so disappointing.

Here's a chance to send a message to "well-meaning" doctors like Healy who might be tempted by easy money and to suffering patients who might not realize that the mild-mannered guy with the stethoscope might have more than their well-being in mind.

sandy.banks@latimes.com



Illinois Doctor Sentenced to Four Consecutive Life Sentences



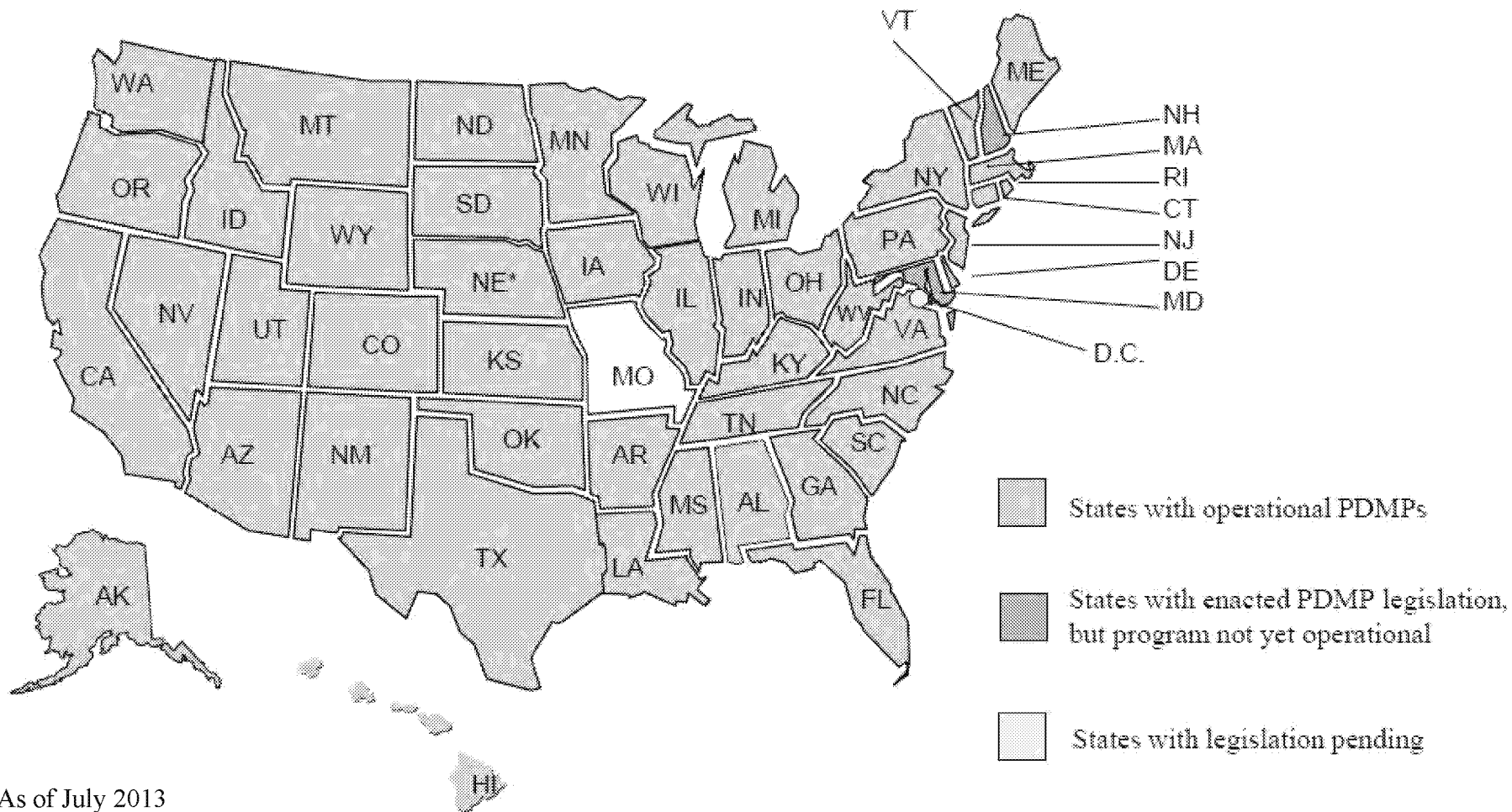
Dr. Paul H. Volkman was sentenced in the Southern District of Ohio on February 14, 2012 to four consecutive life sentences and ordered to forfeit \$1.2 million. Volkman was convicted on 12 counts of illegal distribution of controlled substances, four of which resulted in a death;

one count of conspiracy to distribute controlled substances; four counts of maintaining a drug premise; and one count of possession of a firearm in furtherance of a drug trafficking crime.

From 2003 to 2005, Volkman illegally distributed over 2.5 million dosage units of Schedule II drugs, primarily oxycodone, outside the course of professional practice which resulted in the death of four people. Of the approximate one million practitioner registrants in the United States in 2004, Volkman ranked first in purchases of oxycodone.



Status of State Prescription Drug Monitoring Programs (PDMPs)



Source: The National Alliance for Model State Drug Laws (NAMSDL), www.namsdl.com. "Prescription Drug Abuse: Strategies to Stop the Epidemic (2013)"

* The operation of Nebraska's PDMP is currently being facilitated through the state's Health Information Initiative. Participation by patients, physicians, and other health care providers is voluntary.

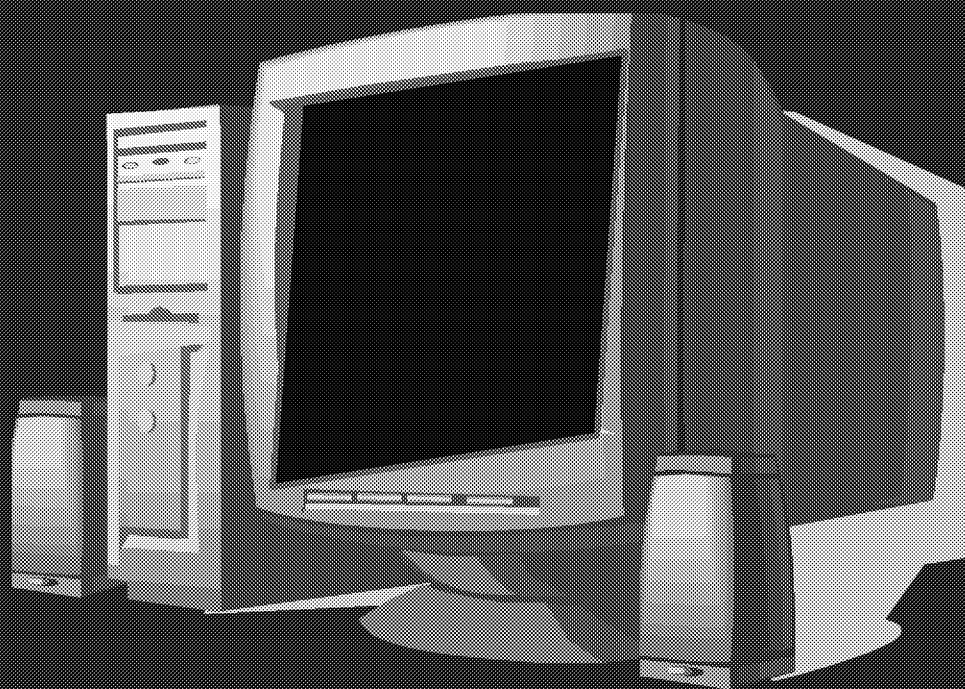


Potential Red Flags

- many customers receiving the same combination of prescriptions
- many customers receiving the same strength of controlled substances;
- many customers paying cash for their prescriptions;
- many customers with the same diagnosis codes written on their prescriptions;
- individuals driving long distances to visit physicians and/or to fill prescriptions;
- customers coming into the pharmacy in groups, each with the same prescriptions issued by the same physician; and
- customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.).



The Internet



Domestic 'Rx' Flow

1. Consumer in Montana orders hydrocodone on the Internet

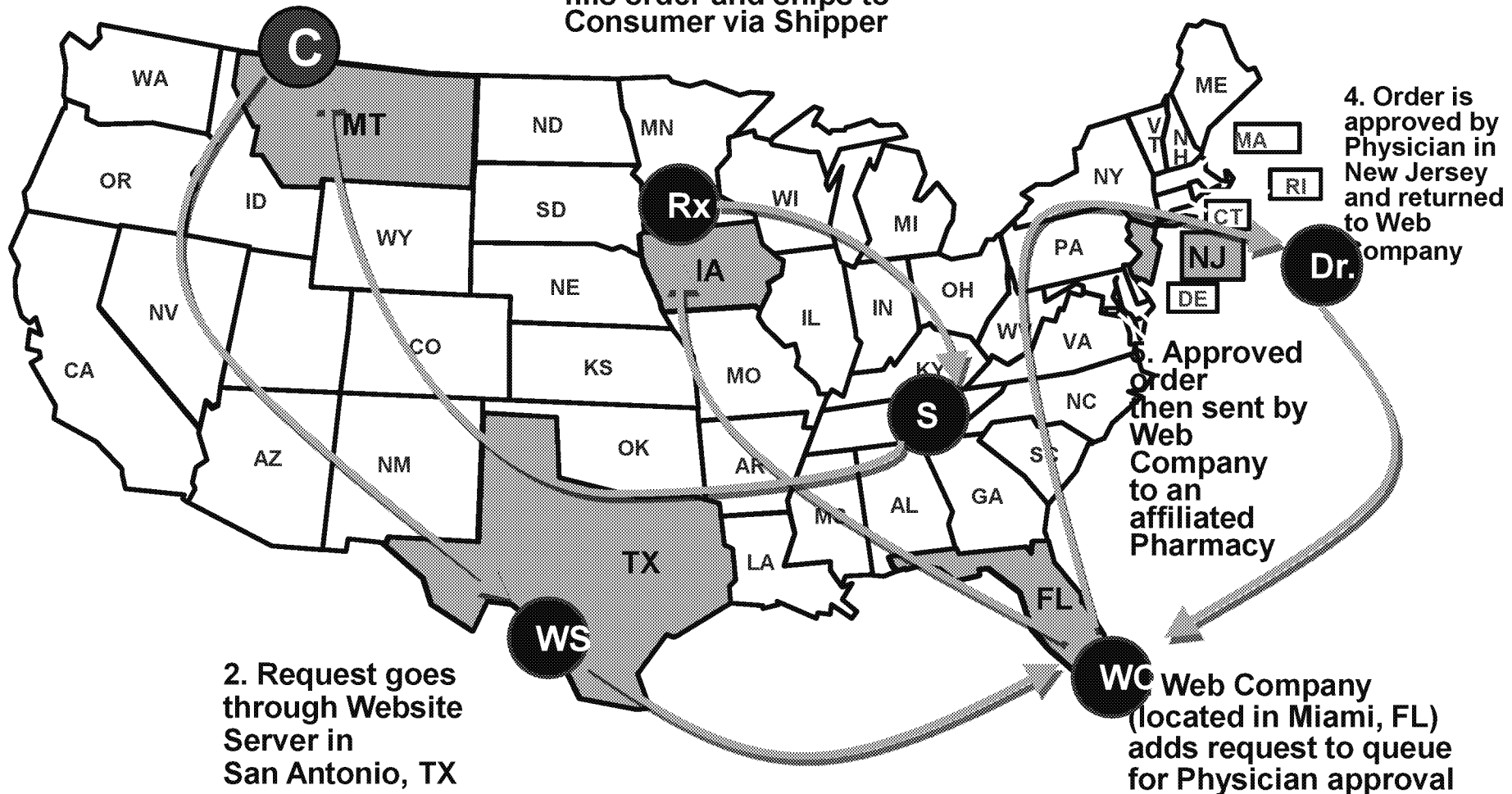
6. Pharmacy in Iowa fills order and ships to Consumer via Shipper

4. Order is approved by Physician in New Jersey and returned to Web Company

5. Approved order then sent by Web Company to an affiliated Pharmacy

2. Request goes through Website Server in San Antonio, TX

3. Web Company (located in Miami, FL) adds request to queue for Physician approval





Purchases of Hydrocodone by Known and Suspected Rogue Internet Pharmacies January 1, 2006 – December 31, 2006

1		Hillsborough	TAMPA	FLORIDA	33614	15,596,380
2		Pinellas	CLEARWATER	FLORIDA	33765	9,077,848
3		Hillsborough	TAMPA	FLORIDA	33614	8,760,876
4		Baltimore City	BALTIMORE	MARYLAND	21213	5,876,300
5		Hillsborough	TAMPA	FLORIDA	33619	5,718,200
6		Jefferson	RIVER RIDGE	LOUISIANA	70123	4,892,900
7		Hillsborough	TAMPA	FLORIDA	33634	4,733,290
8		Polk	LAKELAND	FLORIDA	33813	4,564,480
9		Hillsborough	TAMPA	FLORIDA	33612	4,220,840
10		Pinellas	CLEARWATER	FLORIDA	33759	3,819,320
11		Hillsborough	TAMPA	FLORIDA	33610	3,044,160
12				FLORIDA	33809	3,039,490
13					70123	2,750,000
14					34652	2,664,120
15					33613	1,902,900
16					33801	1,726,020
17		Hillsborough	TAMPA	FLORIDA	33612	1,619,765
18		Hillsborough	TAMPA	FLORIDA	33604	1,570,350
19		Pinellas	TARPON SPRINGS	FLORIDA	34689	1,464,900
20		Lincoln	DENVER	NORTH CAROLINA	28037	1,402,450
21		Hillsborough	TAMPA	FLORIDA	33617	1,282,800
22		Hillsborough	TAMPA	FLORIDA	33619	1,272,860
23		Polk	LAKELAND	FLORIDA	33813	1,039,400
24		Pasco	WESLEY CHAPEL	FLORIDA	33543	1,030,050
25		Iredell	MOORESVILLE	NORTH CAROLINA	28117	902,500
26		Polk	LAKELAND	FLORIDA	33815	867,800
27		Broward	HOLLYWOOD	FLORIDA	33021	865,700
28		Los Angeles	ENCINO	CALIFORNIA	91436	798,100
29		Hillsborough	TAMPA	FLORIDA	33604	793,350
30		Pasco	NEW PORT RICHEY	FLORIDA	34652	583,400
31		Ravalli	FLORENCE	MONTANA	59833	362,000
32		Hillsborough	TAMPA	FLORIDA	33619	162,000
33		Broward	DEERFIELD BEACH	FLORIDA	33441	112,600
34		Hillsborough	TAMPA	FLORIDA	33614	49,600

98,566,711

Date Prepared: 03/07/2007 Source: ARCOS



One Internet Case Example Minneapolis, Minnesota





Total Forfeiture:

\$4,370,258.80



Ryan Haight Online Pharmacy Act: Internet Trafficking a Crime

**21 USC 841(h)(1): It shall be unlawful for
any person to knowingly or intentionally:**

(A) deliver, distribute, or dispense a
controlled substance by means of the
Internet, except as authorized by this title; or

(B) aid or abet any violation in (A)



Ryan Haight Online Pharmacy Act: Violations

Automatic Violation of the CSA if any of the following occurs:

- No in-person medical evaluation by
prescribing practitioner
- Online pharmacy not properly registered
with modified registration.
- Website fails to display required information



Current CSA Registrant Population

Total Population: 1,500,245

➤ Practitioner	-	1,168,919
➤ Mid-Level Practitioner	-	232,136
➤ Pharmacy	-	68,907
➤ Hospital/Clinic	-	15,921
➤ Manufacturer	-	545
➤ Distributor	-	959
➤ Researcher	-	7,164
➤ Analytical Labs	-	1,525
➤ NTP	-	1,319
➤ ADS Machine	-	564

as of 07/31/2013



What took the place of internet controlled substance distribution?

Where did it all go?



Normal Practitioner / Patient Relationship

Practitioners

“A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.” (21 CFR §1306.04(a))

United States v Moore 423 US 122 (1975)



The Florida “Migration”: Was this Normal ??

Vast majority of the “patients” visiting Florida “pain clinics” came from out-of-state:

- Georgia
- Kentucky
- Tennessee
- Ohio
- Massachusetts
- New Jersey
- North and South Carolina
- Virginia
- West Virginia

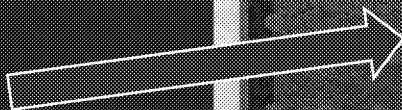


THE MIGRATION





“short waits or
we will pay you”



“earn \$\$\$ for
patient referrals” (sic)

**PAIN CENTER
OF
BROWARD**

LOW PRICES ON MEDS!

2 DOCTORS ON THE PREMISES MEANS NO WAITS

- Be on time for your appointment and we guarantee short waits or we will pay you!! (Details at front desk)
- Still use the Patient Loyalty Program to earn FREE Visits
- Still earn \$\$\$ for patient referrals
- SAME FRIENDLY STAFF AND OWNER

SAVE \$\$
With Our Patient Loyalty Program

\$100 OFF
Initial Visit w/ Ad

Walk-Ins Welcome at 12 Noon Daily.

CALL TODAY FOR APPOINTMENT

954.491.8034

5459 N. FEDERAL HWY • FORT LAUDERDALE, FL 33308
(4 BLOCKS NORTH OF COMMERCIAL)

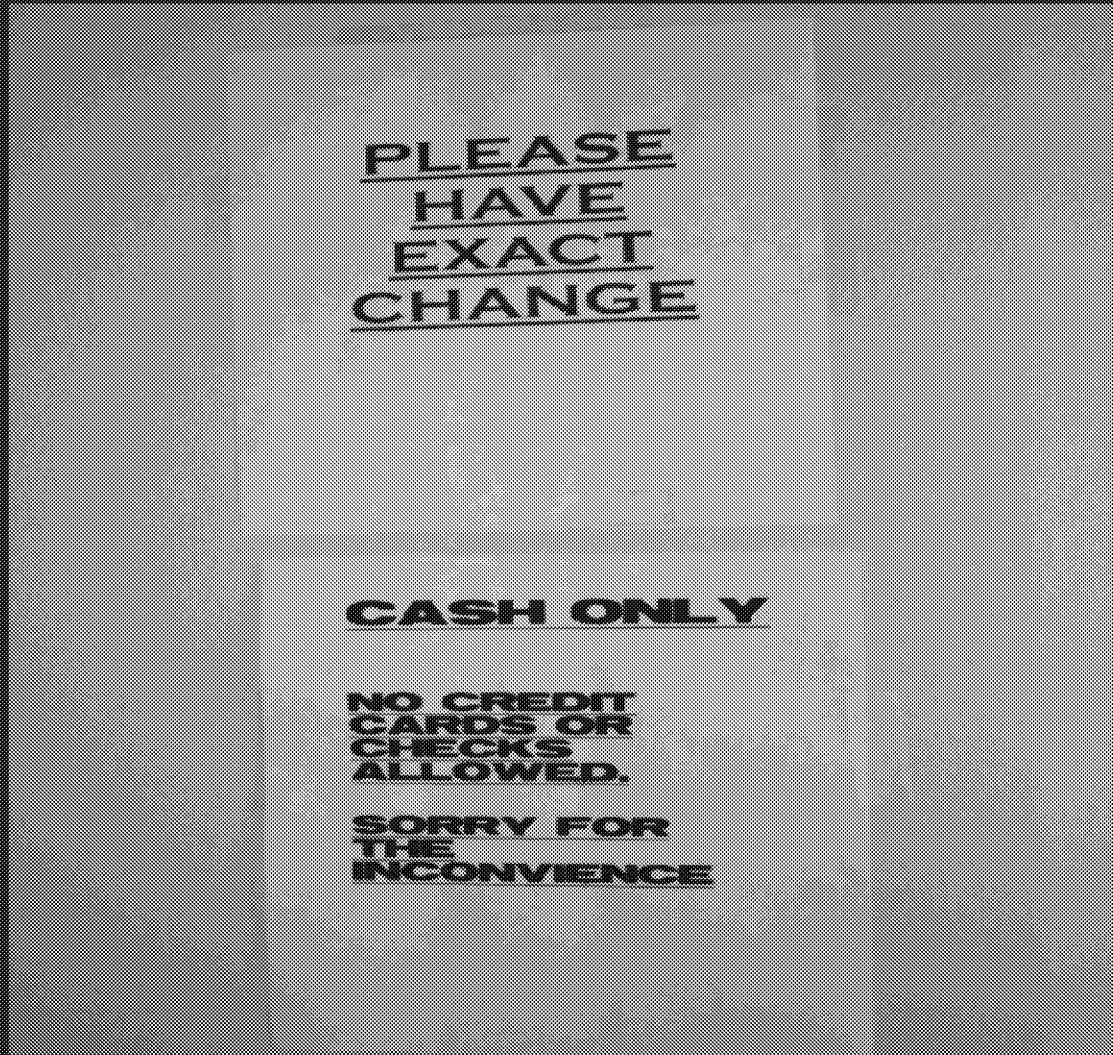


When you get in, make sure you follow the Instructions !!





All the Instructions





All of your weapons !!!!!





Including the knives !!!!





Finally, get your script (s) !!





Make sure you pack them properly for the trip home (which is often out of state) !





Drugs Prescribed

- A 'cocktail' of oxycodone and alprazolam (Xanax[®])
- An average 'patient' receives prescriptions or medications in combination

Schedule II	Schedule III	Schedule IV
Oxycodone 15mg, 30mg	Vicodin (Hydrocodone)	Xanax (Alprazolam)
Roxicodone 15mg, 30mg	Lorcet	Valium (Diazepam)
Percocet	Lortab	
Percodan	Tylenol #3 (codeine)	
Demerol	Tylenol #4 (codeine)	



Average Charges for a Clinic Visit

- Price varies if medication is dispensed or if customers receive prescriptions
- Some clinics advertise in alternative newspapers citing discounts for new patients such as 'buy one get one free' or "50% off with this ad"
- Typically, initial office visit is \$250; each subsequent visit is \$150 to \$200
- Average 120-180 30mg oxycodone tablets per visit



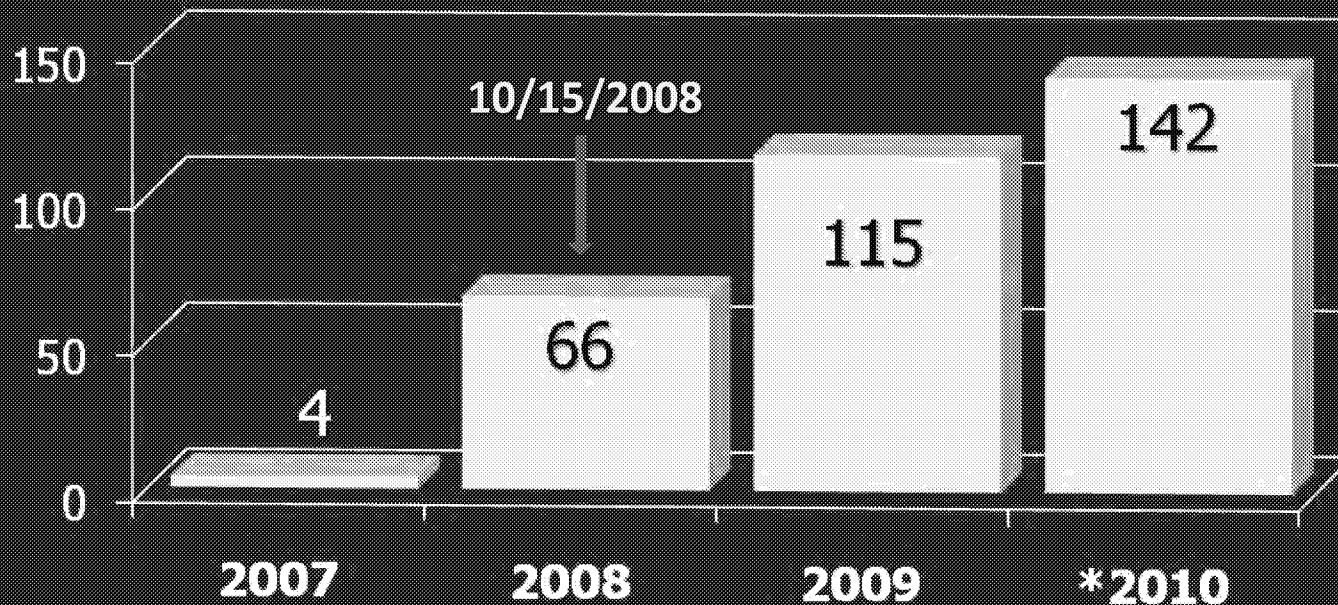
Cost of Drugs

- The ‘cocktail’ prescriptions go for \$650 to \$1,000
- According to medical experts, most clinics do not require sufficient medical history and tests for proper prescribing of Schedule II substances
- Each oxycodone 30mg tablet costs \$1.75 to \$2.50 at the clinics
 - On the street in Florida, that pill can be re-sold for \$7 to \$15
 - Outside of Florida, it can be re-sold for \$25 to \$30 (\$1 per mg)



Explosion of South Florida Pain Clinics

**Estimated Number of
Broward County Pain Clinics**



As of June 4, 2010, Florida has received 1,118 applications and has approved 1026

*As of May 14, 2010, Broward 142; Miami-Dade 79; Palm Beach 111



Explosion of South Florida Pain Clinics – All Providers (Current and Closed)

- All/State of Florida: 1,501
- Broward County: 236
- Miami-Dade County: 156
- Palm Beach County: 161
- Hillsborough County (Tampa area): 214

As of February 12, 2013.



Where to Find Doctors - Craigslist ??

****PHYSICIAN NEEDED, START IMMEDIATELY** (WEST PALM BEACH, FLORIDA)**

Date: 2010-03-03, 5:22PM EST

Reply to: job-gekbz-1627117891@craigslist.org [Errors when replying to ads?]

****PHYSICIAN NEEDED, START IMMEDIATELY****

M.D. / D.O. FOR CONTINUING CARE / PAIN MANAGEMENT CENTER

- FULL TIME & PART TIME POSITIONS ARE AVAILABLE - START IMMEDIATELY!
 - Experience in Pain Management is preferred but NOT necessary. We will train if needed!
 - GREAT Compensation (\$12,000+ PER WEEK!!!)
 - Position may include Medical Director for facility
 - Doctor's need to have their Dispensing License or can obtain one
 - Perfect opportunity for a M.D. / D.O. / or Retiree
 - Please send resume with salary requirements to: DPerezWPM@Gmail.com
- ALL INQUIRES CONTACT: DPerezWPM@Gmail.com OR CALL 561-253-4038

DOCTOR'S NEEDED (MIAMI)

Date: 2010-02-21, 6:50PM EST

Reply to: doctor247@hotmail.com [Errors when replying to ads?]

CAN EARN OVER \$500 DOLLARS AN HOUR
FLEXIBLE HOURS

WEEKDAYS .WEEKENDS OR BOTH
YOU MAKE YOUR OWN SCHEDULE
CONTACT ERIC TEL 305 710-0013

CAN SEND US YOUR CV AT doctor247@hotmail.com

- Location: MIAMI
- Compensation: can earn over \$500 dollars an hour
- This is a part-time job.
- Principals only. Recruiters, please don't contact this job poster.
- Phone calls about this job are ok.
- Please do not contact job poster about other services, products or commercial interests.



Why is this happening?



Its All About Profit

- One case in Florida owner/operator of pain clinic allegedly generated \$40 million in drug proceeds
- Houston investigation \$41.5 million in assets



Its All About Profit

- Another case in Florida - pain clinic operation paid his doctors:
 - \$861,550
 - \$989,975
 - \$1,031,975
 - \$1,049,032
 - \$1,225,775





State of Florida Legislative Actions

- **Effective October 1, 2010**
 - Pain clinics are banned from advertising that they sell narcotics
 - They can only dispense 72-hour supply of narcotics
 - Prohibits the registration of pain clinics unless they are owned by physicians or licensed by non-physicians as a health care clinic
- **Effective July 1, 2011**
 - Clinics must turn over their supply of C-II and C-III controlled substances
 - Clinics are no longer able to dispense these drugs
 - Clinics cannot have ANY affiliation with a doctor that has lost a DEA number



The Washington Post

Feds raid Fla. pill mills; arrest docs, owners

By CURT ANDERSON

The Associated Press

Wednesday, February 23, 2011; 5:23 PM

WESTON, Fla. -- U.S. Drug Enforcement Administration agents and local police swept across South Florida on Wednesday making arrests as part of a lengthy undercover operation into illegal pill mills that dispense huge amounts of powerful prescription drugs across the nation.

The New York Times Reprints

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February 23, 2011

Agents Raid Florida Clinics in Drug Crackdown

By DON VAN NATTA Jr.

MIAMI — Drug Enforcement Administration agents and other law enforcement officials on Wednesday raided six South Florida pain clinics accused of illegally dispensing potent prescription drugs across the United States. Twenty-two people, including trafficking charges.

The Palm Beach Post

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11 arrested in Palm Beach County as part of multi-agency pill mill raid

In Palm Beach County, the raids focused on five doctors in four pain clinics.

By CYNTHIA ROLDAN AND MICHAEL LAFORGIA

Palm Beach Post Staff Writers

Updated: 11:20 a.m. Thursday, Feb. 24, 2011

Posted: 9:57 a.m. Wednesday, Feb. 23, 2011

Operators of four crooked pain clinics in Palm Beach County made millions of dollars by peddling pills to patients with trumped up injuries, rewarding themselves with boats, exotic cars and real estate while rates of overdose deaths and drug-dealing soared, state prosecutors alleged in court documents made public Wednesday.



Clinic response to Enforcement Actions
& the Florida legislation prohibiting
the sale of CS from pain clinics?

Buy Pharmacies or
Move to Other
States!